

REMARKS

Reconsideration is requested.

Minor errors in the specification have been corrected.

The claims have been amended to obviate the basis for the Examiner's objections thereto subject to comments made below regarding certain of the objections.

The manner in which the amendments relate to the Examiner's objections as set out in ¶s 4 and 5, page 2 of the action, is thought to be self-evident. However, it is noted that claim 5 has been amended to depend only from claim 4 while claims 22 and 23 depend only from claim 21.

All of the claims have been amended to include the opening article "A".

Claims 5 and 20-23 have been amended to refer to "A blended composition" in order to avoid confusion with the reference to "blend" as used in claim 5 to define component A, i.e. the blend of claim 4.

With regard to the Examiner's Section 112, 2nd ¶ rejection of claims 1-14 and 17-23, the amendments to claims 5, 8, 9, 10 and 11 should obviate the Examiner's objections as set out in ¶s 9, 11, 12, 13 and 14.

It will be noted, in this regard, that claim 5, as amended, does not depend from multiple claims and the claim also refers to component C as optional. This is thought to be acceptable in the circumstances since the amount of C can range from none at all up to 85 wt % of the composition.

The amendment to claim 8 stresses the fact that the additional materials which are referred to are part of component A.

Markush language has been used in claim 9 and the term "at least partly of" has been deleted as unnecessary from claim 10. The parenthesis have also been deleted from claim 11.

As for the Examiner's other objections, the applicants respond as follows and request reconsideration of the objections for the reasons stated:

**¶ 6:**

It is respectfully submitted that the term “low” in the definition of molecular weight is not indefinite in the context of the applicants’ invention. Those in the art would know exactly what the applicants are referring to, particularly in view of the applicants’ disclosure of the analytical technique used to determine the compounds involved. See, in particular, the paragraph bridging pages 1-2 of the applicants’ specification, and especially page 2, lines 6-13 thereof. Accordingly, reconsideration of the objection to the term “low” is requested.

**¶ 7:**

Similarly, it is respectfully submitted that those in the art would understand the metes and bounds of the applicants’ reference to “natural extracts”. This means the extracts from natural sources such as the extract from fruit skins (i.e. not synthetic products). The terminology is not in any sense indefinite and those in the art would know what the applicants mean.

**¶ 8:**

The term “off taste” is well understood by those in the art. It is a problem presented by many natural products. It means that the products in question have a taste that is not appreciated by the users. The term “off taste” is used much like “off color” to indicate that something is not right, in this case, the taste. There are trained taste experts or panels that exist for the purpose of determining whether or not there is an “off taste” and the extent thereof. There obviously can be no specific quantitative definition as to what constitutes “off taste”; it is determined by experts who recognize that something simply does not taste as it should. In the circumstances, the term “off taste” is definite and understandable to those in the art.

**¶ 10:**

The Examiner is referred to page 3, lines 7-20 of the applicants' disclosure. N values are conventionally used, as those in the art will know, to indicate solid fat content at a particular temperature. In the case of N20, this is the solid fat content at 20°C.

For the reasons indicated, the Examiner is requested to reconsider and withdraw the Section 112, 2nd ¶ rejection of the claims.

The Examiner is also requested to reconsider the Section 103(a) rejection of claims 1-14 and 17-23 as unpatentable over U.S. Patent 5,948,460 ('460) in view of U.S. Patent 4,752,606 ('606) and SU 827066 (SU '066). The references do not make the applicants' invention obvious.

It is noted that there is really no motivation in the references to make the selections from the references that the Examiner has found necessary for the purpose of rejecting the claims. Manifestly, to support a Section 103(a) rejection, there has to be some motivation or suggestion in the art to make the Examiner's combination of references. There is no such motivation here. The Examiner's combination is based purely on hindsight in the light of the applicants' disclosure.

The Examiner describes the applicants' invention as drawn to compositions that contain ursolic acid, oleanolic acid, a glyceride, palm oil and sunflower oil. The applicants' invention is, of course, broader than the way it has been characterized by the Examiner. This is evident, for example, from applicants' claims 1-5. Claim 6 is specific to the use of palm oil while claim 7 calls for sunflower oil.

U.S. '460 is concerned with reducing the metallic aftertaste of artificial sweeteners when used in food products. To do this, the patentees add a very small amount of ursolic acid and/or oleanolic acid to the food product containing the artificial sweetener. The ursolic acid and oleanolic acid which are used are commercial products from Aldrich Chemicals. No particulars are given in terms of presence or absence of apolar and low molecular weight compounds in the ursolic and oleanolic acids as required by the applicants. The '460 patent thus says nothing about this essential feature of the applicants' invention.

The applicants' invention is based on the finding that ursolic acid and oleanolic acid themselves display an off taste and the applicants have identified the components in extracts comprising the ursolic acid and/or oleanolic acid which are responsible for this off taste. The '460 patent is, in no way, appreciative of the problem dealt with by the applicants or their solution to this problem.

Moreover, the applicants have found ways to remove the undesired components from ursolic acid and oleanolic acid, thus providing novel compositions that can be used as health components in health foods free from the undesired off taste which conventional extracts of ursolic acid and oleanolic acid contain.

The reference only teaches that ursolic and oleanolic acids can be used to reduce the metallic aftertaste of a food that contains an artificial sweetener. The reference says nothing about dealing with the undesirable taste caused by the contaminants normally associated with conventional extracts of ursolic and oleanolic acids. The applicants' novel compositions can be with advantage used both in foods containing an artificial sweetener and in foods free of artificial sweetener. In both instances, the off taste due to the presence of the ursolic acid and/or oleanolic acid of the prior art is avoided. Accordingly, it is respectfully submitted that the applicants' claims distinguish patentably from the '460 patent, particularly since the applicants' invention solves a problem not disclosed or dealt with in the patent and deals with the problem in a completely novel fashion.

The Examiner's secondary references do not fill in the substantive deficiencies of the '460 patent. As earlier noted, there is no motivation in the art to combine the references as the Examiner has done to reject the applicants' claims. However, even if the references are considered together, they do not suggest the applicants' invention.

For one thing, the Examiner is incorrect in the interpretation of SU '066. Thus, the Examiner states that the applicants' ursolic acid composition is made in the same way as disclosed in SU '066. However, this is not correct. According to SU '066, catmint is extracted (whereas the applicants use fruits skins) and the SU '066 extraction is carried out twice with acetone at 18 to 20°C whereas the applicants use temperatures of 10°

below boiling point to boiling point. See, for example, the ¶ bridging pages 6 and 7 of the applicants' specification. According to SU '066, the combined extracts after removal of  $\frac{3}{4}$  of the acetone and filtering are redissolved in hot acetone followed by cooling and addition of small amount of water. In contrast, the applicants redissolve in a mixture of water and acetone and then cool to room temperature.

There are, in short, fundamental differences between the applicants' preparation of the ursolic and oleanolic acid compositions and the process used in SU '066. These differences are highlighted in, for example, applicants' claim 15. In any case, however, it is clear that the applicants' method of preparing their ursolic acid composition is fundamentally different from the SU '066 method. Furthermore, there is no suggestion in SU '066 to use the reference compositions in the '460 invention and certainly no suggestion in either reference that the SU '066 ursolic acid composition would be free from the undesired taste of ursolic acid extracts. SU '066 does not even refer to the off taste problem of such extracts and cannot, therefore, be suggestive of the applicants' invention.

The same conclusion is inescapable with respect to U.S. '606. The Examiner refers in particular to Example 1 of the '606 reference. In this example, grape husk is treated with a solvent, e.g. acetone, to obtain an extract of oleanolic acid in solvent. This extract is treated with aqueous base to convert the acid into a water-soluble salt and the salt is purified by removal of the non acids and acidified again whereupon the free acid is isolated by, e.g. extraction and removal of the solvent, whereupon the product can be recrystallized. This process is different from the applicants' process and insufficient information is given as to the nature of the reference product to make any fair comparison with the applicants' ursolic acid compositions as used in the present invention.

Furthermore, U.S. '606 is not in any sense related to the applicants' problem of dealing with the off taste of ursolic acid and oleanolic acid in foods and cannot possibly, therefore, be suggestive of the applicants' solution to this problem.

In connection with the foregoing, it is noted that the Examiner concludes that a man skilled in the art would recognize the benefits of using high purity extracts taught by

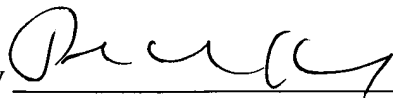
references U.S. '606 and SU '066 and thus would be motivated to use the ursolic acid/oleanolic acid, extracted by the methods according to U.S. '606 or SU '066 in the compositions according to U.S. '460.

In response, the applicants note that the Examiner has no basis for concluding that the applicants' extracted products are the same as the products of U.S. '606 or SU '066 or are made in the same way. In any case, however, the man skilled in the art could not be motivated to use the U.S. '606 or SU '066 products in the '460 invention to deal with a problem not disclosed in the '460 patent. At most, there could only be motivation to use these products in foods containing an artificial sweetener to reduce the metallic aftertaste thereof. Even then, he could not be sure that as a result of the process disclosed in U.S. '606 or SU '066, no components would have been removed that are responsible for the reduction in metallic aftertaste. If the man skilled in the art became aware of the off taste related to the use of the ursolic acid/oleanolic acid from the prior art, he would not have known what to do about this in the absence of the applicants' invention. It was the applicants who discovered that the undesirable taste given to food products by ursolic acid and/or oleanolic acid was caused by components associated with these acids. The art does not refer to this off taste problem caused by these acids and cannot suggest the solution thereto.

In view of the foregoing, favorable reconsideration and allowance are requested.

Respectfully submitted,

MORGAN LEWIS & BOCKIUS LLP

By 

Paul N. Kokulis  
Reg. No. 16773

PNK:mh  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Phone: (202) 739-3000  
Facsimile: (202) 739-3001  
Direct: (202) 739-5455

APPENDIX  
Version with Markings to Show Changes Made

IN THE SPECIFICATION

Page 1, 1st ¶, beginning at line 3, amended to read as follows:

Ursolic acid and oleanolic acid are known compounds that are also known for their health effects[;references]. References wherein these effects are disclosed are, e.g. [eg] JP 09/040 689; JP 09/067 249; CN 1 085 748; JP 1 039 973; JP 03/287 531; JP 03/287 430; EP 774 255; JP 07/258 098; JP 07/048 260; JP 01/132 531; FR 2 535 203; and JP 1 207 262. Compositions comprising ursolic acid and oleanolic acid in weight ratios of 1:99 to 99:1 can be obtained by extracting natural sources like fruit skins or herbs, in particular by extracting skins of apples, pears, cranberries, cherries and prunes. The extracts so obtained contain ursolic acid and oleanolic acid in amounts of about 5-60% and in weight ratios mentioned above. However, these extracts have a major drawback, i.e. [ie] the extracts display a severe negative off flavour and as the components are intended to be used as health components in food products and the consumer does not appreciate a negative off flavour while consuming his food, it would be a main advantage when mixtures of these components could be obtained containing sufficient amounts of ursolic acid and oleanolic acid to make them useful for application in foods as health component and that do not display the negative off flavour of the products available so far.

Page 1, 2nd ¶, beginning at line 26, amended to read as follows:

We [studies] studied whether we could obtain such products. In this study, we found that the negative off flavour of the ursolic acid/oleanolic acid mixture is due to the presence of natural apolar and/or low molecular weight components in the natural extracts known so far. The apolar components being defined as that fraction of an extract from fruit skins that is eluted from a polar silica gel column, preferably with a Alltech Econosphere Silica HPLC column (150\*4.6 mm, 5 µm) with an eluent, preferably being either a mixture of hexane/toluene (50:50) or a mixture of toluene/ethylacetate/formic acid

(500/200/16), in 0-7 min. Low molecular weight components are detected by GC with a apolar column, preferably a Chrompack SIMDIST (10m\*0.53 mm, 0.1 µm filmthickness) or a Quadrex DB-5 (10m\*0.53 mm, 0.1 µm filmthickness) and a temperature program, preferably starting with [120 oC] 120°C (1 min); then [20 oC] 20°C/min until [325 oC] 325°C, then [5 oC] 5°C/min until [350 oC] 350°C (5 min) with retention times from 0.5-7 min. The preferred used carrier gas is hydrogen with a pressure of 15 psi.

Page 2, 2nd ¶, beginning at line 30, amended to read as follows:

Although the above mix could be used as such in food products, it is preferred to use it as a blend with other components, in particular, as a blend with glycerides, preferably triglycerides. Therefore, our invention concerns blends of a health component and a glyceride wherein the health component is the mixture disclosed above and which blend contains 1 to 99 wt %, preferably 5-80 wt % of one or more components selected from mono-, di-, and triglycerides as the glyceride. The glyceride part of this blend preferably displays a solid fat content [masured] measured by NMR-pulse on a non-stabilised fat at the temperature indicated of:

5 to 90 at [ 5 oC] 5°C

2 to 80 at [20 oC] 20°C and

less than 15, preferably less than 10 at [35 oC] 35°C.

The solid fat content is measured by the well known NMR-pulse technique on a fat that is not stabilised, this means that the measurement was performed on a fat that was subjected to the following treatment:

Melt at [80 oC] 80°C, keep it at [80 oC] 80°C for 15 min, cool it to [0 oC] 0°C and keep it at [0 oC] 0°C for 30 min, heat it to [measuremt] measurement temperature and keep it thereon for 30 min and measure the N-value at this temperature.



IN THE CLAIMS

The claims are amended as follows:

1. (Twice Amended) [Blend] A blend of a health component and a glyceride, wherein the health component is a mixture comprising ursolic acid and oleanolic acid in a weight ratio of 1:99 to 99:1, wherein the mixture contains less than 20 wt % of the natural apolar and/or low molecular weight components as present in natural extracts for ursolic acid and oleanolic acid, and wherein the blend contains 1-99 wt % of one or more components selected from mono-, di- and triglycerides as the glyceride.

2. (Amended) [Blend] A blend according to claim 1 wherein the natural apolar and/or low molecular weight components are the components that provide an off taste to the natural extract and belong to the class of hydrocarbons, alcohols, fatty acids, triglycerides, ketones and carbohydrates.

3. (Twice Amended) [Blend] A blend according to claim 1 or 2 wherein the blend contains 5 to 80 wt % of one or more components selected from mono-, di-, and triglycerides as the glyceride.

4. (Twice Amended) [Blend] A blend according to claim 3 wherein the glyceride part displays a solid fat content measured by NMR-pulse on a non-stabilised fat at the temperature indicated of :

5 to 90 at 5°C

2 to 80 at 20°C and

less than 15 at 35°C.

5. (Twice Amended) [Blend] A blended composition comprising, as component A, a blend according to claim 4 wherein [the blend comprises components A, B and C, wherein:

A = the composition of claims 1 or 2

B =] a solid fat with an N20 of more than 20 as component B and, optionally, as component C,

[C =] a fat having at least 40 wt % of fatty acids with 18 C-atoms and having one to three double bonds,

component A being present in [amounts] an amount of more than 0.1 wt %,

component B being present in [amounts] an amount of 8 to 90 wt % and

component C being present in [amounts] an amount of 0 to 85 wt %.

6. (Amended) [Blend] A blend according to claim 5 wherein fat B is selected from the group consisting of palm oil; palm oil fractions; cocoa butter equivalents; palm kernel oil; fractions of palm kernel oil; hardened vegetable oils such as hardened palm oil; hardened fractions of palm oil; hardened soybean oil; hardened sunflower oil; hardened [rape seed] rapeseed oil; hardened fractions of soybean oil; hardened fractions of rapeseed oil; hardened fractions of sunflower oil; mixtures of one or more of these oils and interesterified mixtures thereof.

7. (Amended) [Blend] A blend according to claim 5 wherein fat C is selected from the group consisting of sunflower oil; olive oil; soybean oil; [rape seed] rapeseed oil; palm oil olein; [cotton seed] cottonseed oil; olein fractions from vegetable oils; high oleic oil; olein fractions from vegetable oils; high oleic vegetable oils such as HOSF or HORP, fish oils; fish oil concentrates and CLA-glycerides.

8. (Amended) [Blend] A blend according to claim 5, wherein [the blend contains a] component A [that] also contains isoflavones and/or flavones in amounts corresponding with 0.005 to 5 % of the total amount of ursolic acid and oleanolic acid.

9. (Amended) [Blend] A blend according to claim 5 wherein component A is a component isolated from fruit skins [such as] selected from the group consisting of skins from apples, pears, cranberries, cherries [or] and prunes.

10. (Twice Amended) [Food products] A food product with a fat phase comprising [at least partly] the blend according to claim 1.

11. (Amended) [Food products] A food product according to claim 10 wherein the food product is selected from the group consisting of spreads having [(fat contents of 10 to 90 wt %)]; dressings; mayonnaises; cheese; ice creams; ice cream coatings; confectionery coatings; fillings; sauces and culinary products.

12. (Twice Amended) [Food products] A food product according to claim 10 or 11 wherein the food product comprises 10 to 90 wt % of a continuous fat phase.

13. (Twice Amended) [Food supplements] A food supplement comprising the blend according to claim 1 in encapsulated form.

14. (Amended) [Food supplements] A food supplement according to claim 13, wherein the encapsulating material is selected from: sugars, carbohydrates, gums, hydrocolloids and gelatin.

17. (Amended) [Blend] A blend according to claim 1 wherein the weight ratio of ursolic acid to oleanolic acid is 5:95 to 95:5 and the mixture contains less than 10 wt % of the natural apolar and/or low molecular weight components.

18. (Amended) [Blend] A blend according to claim 1 wherein the weight ratio of ursolic acid to oleanolic acid is 15:85 to 85:15 and the mixture contains 1 to 6 wt % of the natural apolar and/or low molecular weight components.

19. (Amended) [Blend] A blend according to claim 4 wherein the glyceride part displays a solid fat content measured by NMR-pulse on a non-stabilised fat of less than 10 at 35°C.

20. (Amended) [Blend] A blended composition according to claim 5 wherein component B is a solid fat with an N20 of more than 45.

21. (Amended) [Blend] A blended composition according to claim 20 wherein component B is a solid fat with an N20 of more than 60.

22. (Amended) [Blend] A blended composition according to claim [20 or] 21 wherein component A is present in an amount of 0.1 to 20 wt %, component B is present in an amount of 25 to 75 wt % and component C is present in an amount of 15 to 65 wt %.

23. (Amended) [Blend] A blended composition according to claim [20 or] 21 wherein component A is present in an amount of 0.2 to 10 wt %, component B is present in an amount of 40 to 70 wt % and component C is present in an amount of 20 to 50 wt %.